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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,684	04/19/2001	Franklin Okumu	10466/18	1800

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,684	OKUMU, FRANKLIN	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 March 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040614*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on June 14, 2004 has been entered.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-52 are rejected under 35 U.S.C. 103(a) as being obvious over the European Patent Application 0 216 485 in view of Tipton et al (U.S. Patent No. 5,747,058). The European Patent Application '485 teaches compositions comprising a complex of a growth hormone and a metal, preferably zinc, in combination with a thickened oil vehicle comprising mineral oil or vegetable oil, and optionally in combination with adjuvants or excipients which further extend the release rate of the metal-complexed growth hormone. Preferred oil vehicles are mixtures of peanut oil and aluminum monostearate, and mixtures of soybean oil and beeswax. The molar ratio of zinc to growth hormone is at least 1:1, preferably at least 2:1. The compositions are injected or introduced into an animal as an implant. See, e.g., page 2, lines 20-23; page 3, lines

14-17; and page 3, line 24 - page 4, line 22. The European Patent Application '485 teaches the use of biocompatible thickened oil vehicles in general (see, e.g., page 3, lines 29-32, and claim 10), but does not teach Applicant's particularly claimed carrier material comprising sucrose acetate isobutyrate and a solvent. Tipton et al disclose high viscosity liquid controlled delivery systems comprising a component (HVLCM) that has a viscosity of at least 5,000 cP at 37°C and that does not crystallize neat under ambient or physiological conditions. A preferred component is sucrose acetate isobutyrate (SAIB). The delivery systems can include solvents such as ethanol, propylene carbonate, and benzyl alcohol, which lower the viscosity of the delivery system, e.g. to less than 1000 cP or less than 200 cP, for purposes of administration and which then dissipate or diffuse, leaving a highly viscous implant. Ratios of SAIB:solvent of 60:40 and of 70:30 are exemplified. By selection of the HVLCM and the solvent, a wide variety of pre- and post-administration composition viscosities can be achieved. The delivery systems can be used for the controlled release delivery of substances such as natural and synthetic bioactive peptides and proteins, including growth factors. The substances to be delivered can preferably be present in amounts ranging from about 2 % to about 10% by weight. See, e.g., the Abstract; column 2, lines 47-67; column 8, lines 16-25 and 41-49; and column 14, lines 1-18. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use the delivery system of Tipton et al as the biocompatible thickened oil vehicles of the European Patent Application '485 because the European Patent Application '485 is not limited to the use of any particular biocompatible thickened oil vehicle, because the delivery system of Tipton et al is disclosed to be useful in delivering the same types of biologically active substances, i.e. proteins including growth factors, which are disclosed by the European Patent

Application '485, and because use of the delivery system of Tipton et al as the biocompatible thickened oil vehicle of the European Patent Application '485 would have the advantage of providing simple controlled delivery systems which are easily formulated and which provide different pre- and post-administration viscosities for ease of administration (see, e.g., column 2, lines 30-67). Neither the European Patent Application '485 nor Tipton et al teach the exact release rates recited in instant claims 27-30, 32-35, and 37-40. However, the European Patent Application '485 does teach that use of the metal complexes of growth hormone allows a slower release rate upon injection than does the free form of growth hormone (see page 2, lines 7-10), and Tipton et al disclose that release rates can be chosen and optimized by appropriate choice of additives (see column 3, lines 30-44, and column 9, lines 1-5). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to adjust the composition of the delivery system in order to optimize the release rates of the European Patent Application '485 as modified above by Tipton et al because the European Patent Application '485 discloses the desirability of a slower release rate upon injection and because Tipton et al disclose that release rate is a result-effective variable and therefore one of ordinary skill in the art would be motivated to optimize such a variable.

4. Claims 1, 2, and 26-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Jeng et al (U.S. Patent No. 6,719,992). Jeng et al disclose extended release compositions comprising sucrose distearate or sucrose stearate, bovine somatotropin, and zinc. The compositions are administered to mammals including rats. See, e.g., the Abstract; column 4, lines 31-45; column 15, Tables 1 and 2; and Example 8. The sucrose distearate and sucrose stearate of Jeng et al are both stearate esters and disaccharide esters. In view of the similarity in structure, function, and

utility between the sucrose distearate and sucrose stearate of Jeng et al and Applicant's claimed liquid material, the former are deemed inherently to be non-water soluble, to have the same viscosity, and to not crystallize neat under ambient physiological conditions to the same extent claimed by Applicant. In view of the similarity in components, function, and utility between the compositions of Jeng et al and Applicant's claimed compositions, the former are deemed inherently to have the same growth hormone release rate as is claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the compositions of Jeng et al and Applicant's claimed compositions to shift the burden to Applicant to provide evidence that the claimed compositions are unobviously different than those taught by Jeng et al.

5. Instant claims 1, 2, and 26-30 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/198,209 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose the liquid materials as generically claimed in instant claim 1, does not disclose multivalent metal cations in general, does not disclose the specific liquid materials recited in instant claim 2, and does not disclose the growth hormone release rates recited in instant claims 27-30.

The disclosure of Jeng et al (U.S. Patent No. 6,719,992) relied upon in the above rejection is deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of its provisional application, 60/214,168, because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the same subject matter. See, e.g., the Abstract; page 7, lines 6-13; pages 25-26, Tables 1 and 2; and Example 8.

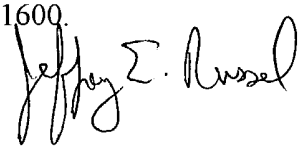
Accordingly, Jeng et al is deemed to be prior art under 35 U.S.C. 102(e) against instant claims 1, 2, and 26-30.

6. The examiner maintains his position for the reasons set forth during prosecution of the parent application.

7. If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate that the copy was not readily available, it is because the copy could not be readily obtained when the Office action was mailed. Should applicant desire a copy of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

July 1, 2004